REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. *See* MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to meet any of the three basic criteria.

A. Claims 34-36, 38, and 42 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 20010020181 to Layne (the *Layne* application) in view of U.S. Patent No. 6,096,070 to Ragheb, *et al*. (the *Ragheb* patent).

The *Layne* application discloses that a series of spaced apart ePTFE circumferential bands can then be placed over the top of longitudinal strips and ringed stents. All of the components of the structure are then laminated to the inner ePTFE tube to capture the stent. By selecting the size and position of the ePTFE bands, it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. *See* Abstract. The ePTFE tube connected to the stent prevents cellular infiltration through the stent and restenosis. *See* ¶ [0007]. The *Layne* application does not disclose use of a drug or therapeutic agent with the ePTFE circumferential bands, inner ePTFE tube, stent, or any component.

The *Ragheb* patent discloses a coated implantable medical device such as a coronary stent with at least one layer of a bioactive material posited on one surface, and at least one porous layer posited over the bioactive material layer. The porous layer is comprised of a polymer applied preferably by vapor or plasma deposition and provides a controlled release of the bioactive material. *See* Abstract. Degradation of an agent, a drug or a bioactive material applied to a vascular stent or other implantable medical device may be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer that is applied

without the use of solvents, catalysts, heat or other chemicals or techniques, which would otherwise be likely to degrade or damage the agent, drug or material. *See* column 3, lines 7-20.

First, the Applicant respectfully asserts that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. The *Layne* application is directed to the problem of providing an ePTFE tube on a stent and the *Ragheb* patent is directed to the problem of avoiding drug degradation in the coating process. In addition, the *Layne* application has a completely different principle of operation than the *Ragheb* patent. The *Layne* application uses the ePTFE tube without any drug to prevent restenosis, while the *Ragheb* patent relies on bioactive materials. *See* the *Layne* application at ¶ [0007] *versus* the *Ragheb* patent at column 5, lines 48-51. The former operates without the use of drugs while the latter requires them. Therefore, there is no motivation to combine the *Layne* application and the *Ragheb* patent, and to do so is impermissible hindsight.

Second, the Applicant respectfully asserts that there is no reasonable expectation of success. The *Layne* application discloses a drug-free system for structurally supporting an ePTFE tube on a stent and the *Ragheb* patent discloses applying a porous coating over a drug on a stent. One of ordinary skill in the art would not expect success in combining the inventions of the *Layne* application and the *Ragheb* patent to produce a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as claimed by the Applicant.

Third, the Applicant respectfully asserts that the *Layne* application and the *Ragheb* patent, alone or in combination, fail to teach or suggest all the claim limitations. The cited references fail to disclose, teach, or suggest a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as recited in independent claims 34, 35, 36 and 42.

The cited references fail to disclose a band comprising a polymer containing a therapeutic agent. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See* Abstract. As noted by the Examiner, the *Layne* application is silent regarding the bands containing different therapeutic agents, but the *Layne* application is also silent as to the bands containing any therapeutic agent. The terms "drug" or "therapeutic agent" do not appear in the *Layne* application, which operates according to the principle that the ePTFE tube prevents cellular infiltration through the stent and restenosis. *See* ¶ [0007]. Therefore, no

drug is necessary in the *Layne* application. The *Ragheb* patent discloses a coated implantable medical device, but the coating is applied to the surface of the stent and not to a band. *See* Abstract. The *Ragheb* patent fails to disclose a band or any other component wrapped around the stent.

The cited references also fail to disclose a band elastically gripping the stent. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See* Abstract. The strips and/or bands are configured in the desired pattern onto each of the structures, the structures are exposed to heat and pressure, thereby causing the ePTFE regions of the strips and/or bands to fuse or laminate to the tubular graft. *See* ¶ [0021]. Therefore, the *Layne* application depends on fusing the ePTFE circumferential bands to the tubular graft to retain the ePTFE circumferential bands on the stent, rather than depending on elastically gripping the stent. In fact, the ePTFE material, which is the only band material disclosed in the *Layne* application, is inelastic and so incapable of gripping the stent. PTFE is stretched to several hundred percent of its original length to form ePTFE. *See* ¶ [0006]. Radial expansion of a stent may stress and tear an ePTFE cover. *See* ¶ [0007]. Therefore, the band of the *Layne* application is not elastic and cannot elastically grip the stent. The *Ragheb* patent fails to disclose a band, let alone a band capable of elastically gripping the stent.

Claim 38 depends directly from independent claim 34 and so includes all the elements and limitations of its independent claim. The Applicant therefore respectfully submits that the dependent claims are allowable over the *Layne* application and the *Ragheb* patent for at least the same reasons as set forth above with respect to its independent claim.

Withdrawal of the rejection of claims 34-36, 38, and 42 under 35 U.S.C. §103(a) as being unpatentable over the *Layne* application in view of the *Ragheb* patent is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,
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